Appl. No. 09/628,186

Preliminary Amendment dated May 28, 2004

Responsive to the office action of January 5, 2004

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Attorney Ref. No.: 037003-0280721

I. AMENDMENT

IN THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1. (Currently amended) A method for radiolabeling a chelator-conjugated protein,

ligand or peptide with a therapeutic radioisotope for administration to a patient comprising

(i) mixing the chelator-conjugated protein, ligand or peptide with a solution

comprising the therapeutic radioisotope or salt thereof, and

(ii) incubating the mixture for a sufficient amount of time under amiable

conditions such that a radiolabeled protein, ligand or peptide having radiochemical purity

radioincorporation greater than 95%, sufficient binding specificity, and a specific activity of

at least about 5 mCi/mg, is achieved such that the radiolabeled protein, ligand or peptide may

be administered directly to the patient without further purification.

2. (Original) The method of claim 1, wherein said therapeutic radioisotope is

selected from the group consisting of alpha and beta emitters.

3. (Original) The method of claim 2, wherein said therapeutic radioisotope is a beta

emitter.

4. (Original) The method of claim 3, wherein said beta emitter is ⁹⁰Y.

5. (Previously presented) The method of claim 1, wherein said protein or peptide is

an antibody or antibody fragment.

6. (Original) The method of claim 4, wherein said sufficient incubation time is less

than about eight minutes.

7. (Original) The method of claim 6, wherein said sufficient incubation time is

between about 30 seconds to about five minutes.

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8. (Original) The method of claim 1, wherein said chelator is a bifunctional chelator selected from the group consisting of MX-DTPA, phenyl-DTPA, benzyl-DTPA, CHX-DTPA, DOTA and derivatives thereof.

- 9. (Original) The method of claim 8, wherein said chelator is MX-DTPA.
- 10. (Original) The method of claim 4 wherein said amiable conditions refer to acceptable temperature, pH and buffer conditions.
- 11. (Original) The method of claim 10, wherein said acceptable temperature ranges from about 25°C to about 50°C.
- 12. (Original) The method of claim 10, wherein said acceptable pH ranges from about 3 to about 6.
- 13. (Original) The method of claim 10, wherein said acceptable buffer is an acetate buffer.
- 14. (Original) The method of claim 13, wherein said buffer is sodium acetate is at a concentration of between about 10 and about 1000 mM.
- 15. (Original) The method of claim 10, where said acceptable buffer includes a benign radioprotectant.
- 16. (Original) The method of claim 15, wherein said benign radioprotectant is ascorbate.
 - 17. (Canceled)
- 18. (Original) The method of claim 1, wherein said binding specificity is at least 70%.
 - 19-48. (Canceled)

- 49. (Previously presented) The method of claim 6, wherein said sufficient incubation time is about three minutes.
- 50. (Previously presented) The method of claim 6, wherein said sufficient incubation time is about five minutes.
- 51. (Previously presented) The method of claim 4, wherein said sufficient incubation time is about ten minutes.
- 52. (Previously presented) The method of claim 1, wherein a level of radioincorporation of at least about 96 % is achieved.
- 53. (Previously presented) The method of claim 1, wherein a level of radioincorporation of at least about 97 % is achieved.
- 54. (Previously presented) The method of claim 1, wherein a level of radioincorporation of at least about 98 % is achieved.
- 55. (Previously presented) The method of claim 1, wherein a level of radioincorporation of at least about 99 % is achieved.
- 56. (Previously presented) The method of claim 5, wherein the protein or peptide is an antibody fragment selected from the group consisting of Fab, F(ab')₂, and Fv fragments.
- 57. (Previously presented) The method of claim 5, wherein the protein or peptide is a therapeutic antibody or antibody fragment.
- 58. (Previously presented) The method of claim 57, wherein the protein or peptide binds specifically to CD20.
- 59. (Previously presented) The method of claim 57, wherein the protein or peptide is an antibody fragment selected from the group consisting of Fab, F(ab')₂, and Fv fragments.
- 60. (Previously presented) The method of claim 1, wherein the binding specificity is at least 50 %.

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- 61. (Previously presented) The method of claim 1, wherein the binding specificity is at least 80 %.
- 62. (New) The method of claim 1, wherein a level of radioincorporation greater than 96 % is achieved.
- 63. (New) The method of claim 1, wherein a level of radioincorporation of from 96.3 to 99.5% is achieved.